IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: HAMAMOTO et al.
Serial No. 10/587,862
Filed: July 28, 2006
For: ANTI-INFLAMMATORY ANALGESIC FOR EXTERNAL USE

Art Unit: 1617
Examiner: Sahar Javanmard

DECLARATION

Honorable Commissioner for Patents
Sir

I, Hidetoshi Hamamoto, a citizen of Japan, declare and state as follows.

I am one of the co-inventors of the subject matter of the above-identified application and have complete knowledge of all aspect of the invention embodied therein.

I graduated from the engineering department of Tokushima University, Japan, in 1993, and completed the post graduate course in 1995.

In 1995, I was employed in Teikoku Seiyaku Co., Ltd. and engaged in a research and development work related to an external preparation such as a plaster etc.

After leaving Teikoku Seiyaku Co., Ltd. in 2002, I was employed in MEDRx Co.,Ltd. Since then, I was engaged in a research of formulations such as an external preparation, or an oral jelly formulation etc., and a developing and manufacturing works.

I understand the English language and studied the Official Action dated May 13, 2010 received in said application.

In order to demonstrate that the cited formulation is gelated before use, the said formulation was actually prepared and a degree of gelation was confirmed.

The following experiment was entirely directed and supervised by the inventor of the present invention, Hidetoshi Hamamoto.

1. Preparation of the formulation

A formulation of Example 25 in Mizobuchi et al.(US 6268355) was prepared according to a procedure described in "EXAMPLES 21 TO 27 CATAPLASMS" (the 6th column, lines 45-56).

Ingredient	Amount (g)
aspirin	0.1
isopropyl myristate	0.4
crotamiton	0.5
polyacrylic acid	9
glycerin	10
propylene glycol	20
macrogol 200	20
1,3-butanediol	27.5
magnesium aluminometasilicate	2
polyvinyl pyrrolidone	10
polysolvate 80	0.5
Total	100

First of all, each of ingredients shown in the above table was weighed. Polyacrylic acid and polyvinyl pyrrolidone were added to a mixture of glycerin, propylene glycol, macrogol 200 and 1,3-butanediol at room temperature and dispersed. A base solution of cataplasm was then prepared by warming the mixture up to 60 °C and homogenizing it.

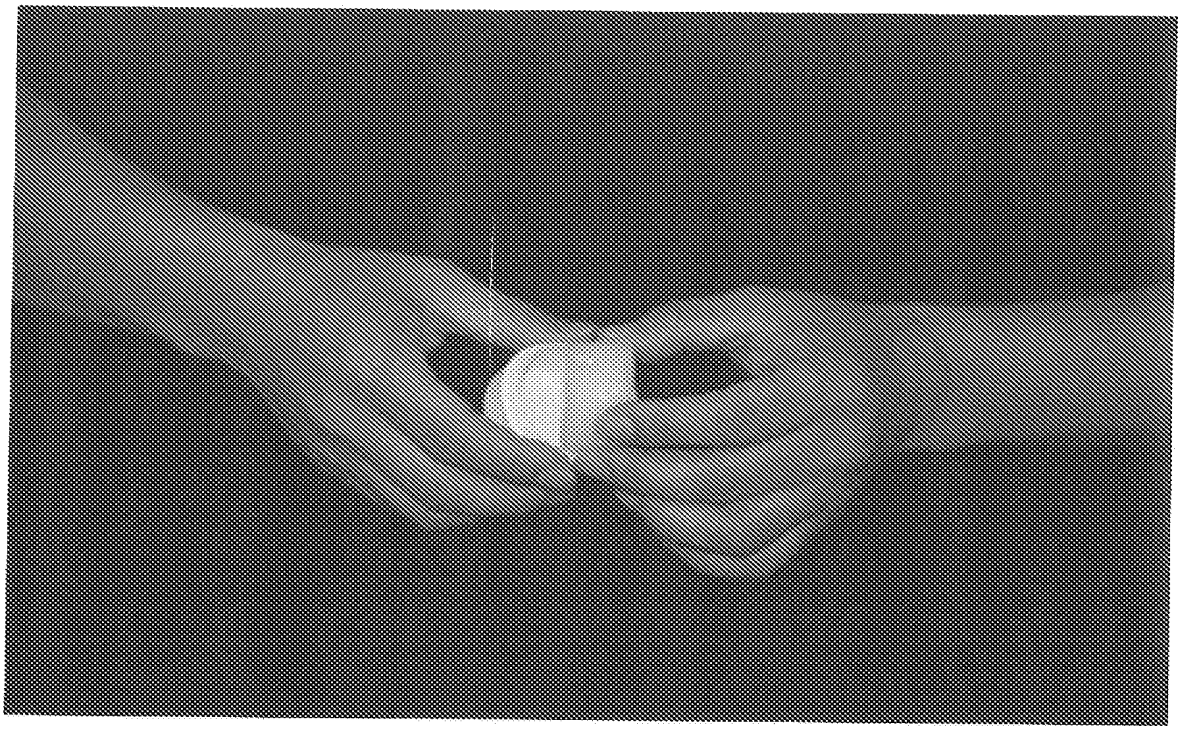
Separately from the base solution, aspirin was dissolved in isopropyl myristate, crotamiton and polysolvate 80, the solution was added at room temperature to the base solution prepared above and magnesium aluminometasilicate was kneaded into the mixture. A container for ointment was filled up with the resulted formulation of Example 25 and sealed.

2. Observation

The container was left stand at room temperature for three days and the formulation was taken out from the container. As shown in pictures, the formulation was turned into an elastic gel composition.

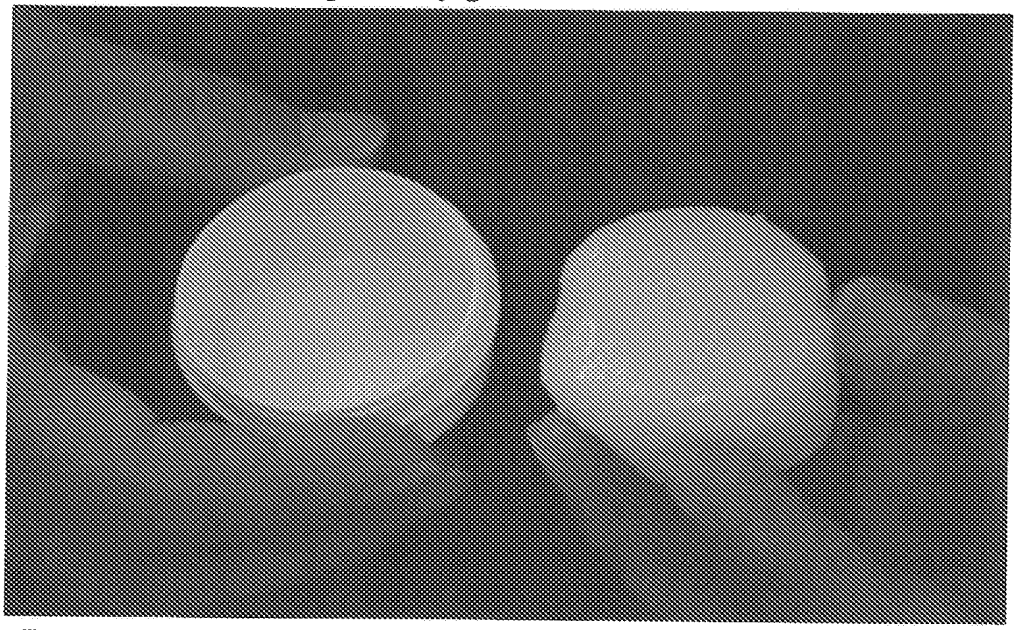
<Pictures 1>

The formulation was taken out from a container after being left stand at room temperature for three days.



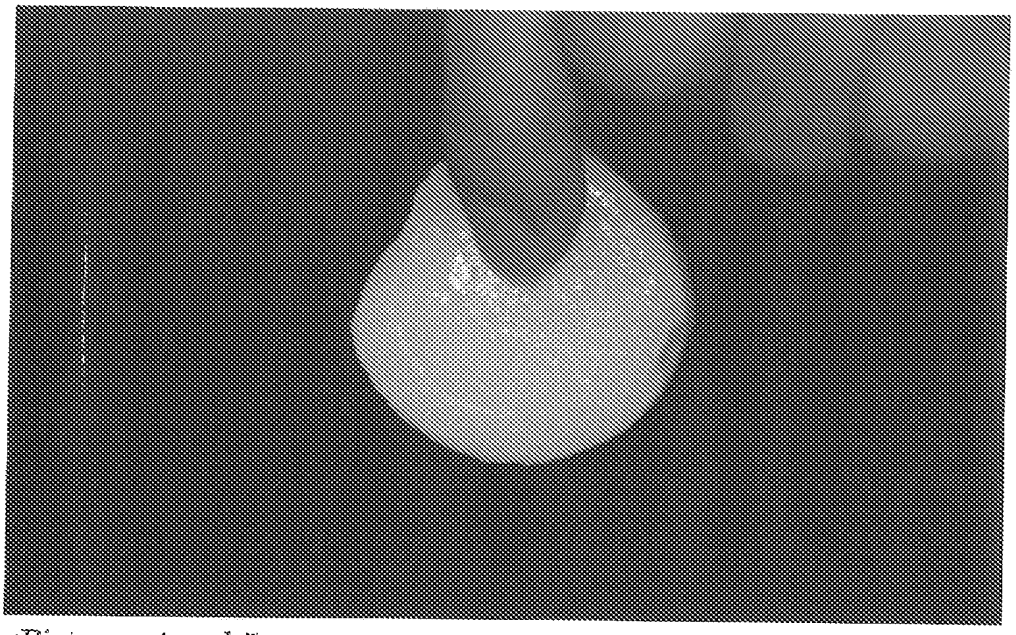
<Picture 2>

The formulation was perfectly gelated.



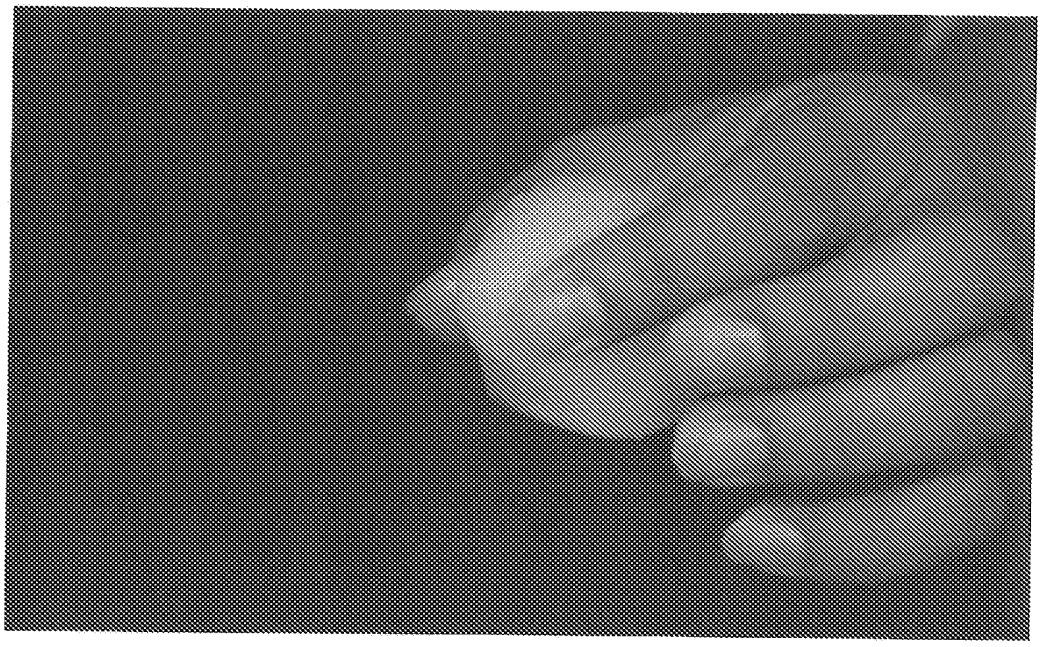
<Picture 3>

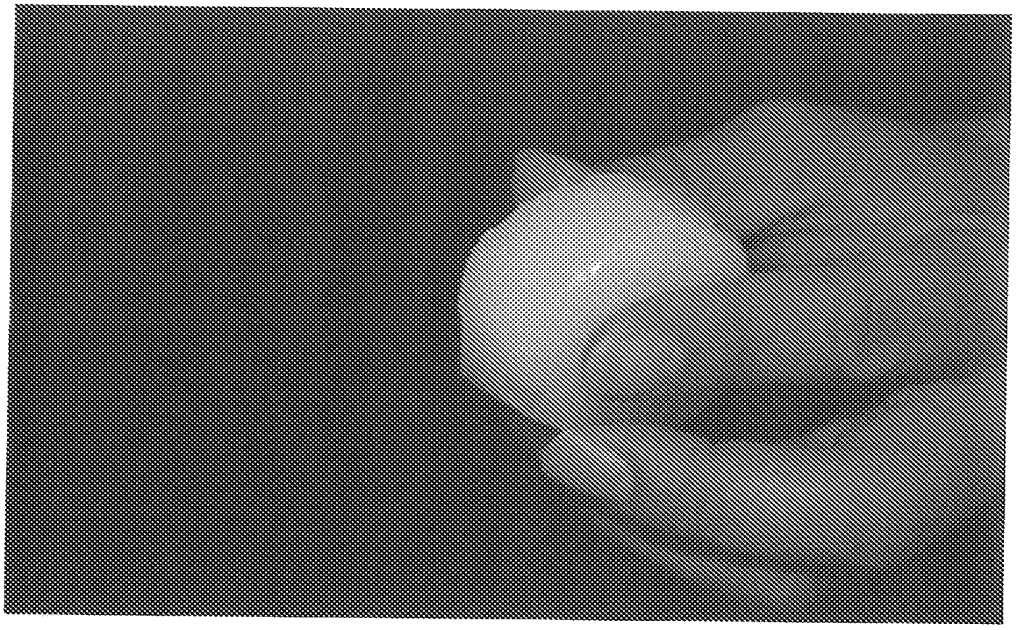
A round shape of the container is perfectly copied to the gel composition.



<Pictures 4 and 5>

The gelated composition is so elastic that the whole shape is recovered if it is pressed by fingers.





It was demonstrated that gelation of the formulation of Example 25 was proceeded in the container and completed in three days, and the formulation was turned into an elastic gel composition, which could not be used to protect wounds by transformation from a sol to a gel during use with easy separation on the gel substantially as a mass after its use.

All statements made herein of our own knowledge are true and all statements made an information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

This 8th day of October, 2010

Hidetoshi Hamamoto

Hidetoshi HAMAMOTO